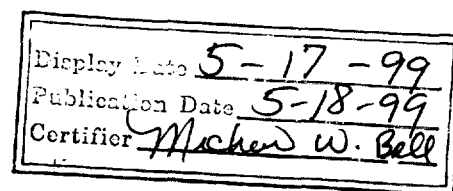


DEPARTMENT OF HEALTH AND HUMAN SERVICES



Food and Drug Administration

21 CFR Part 558

**New Animal Drugs for Use in Animal Feeds; Fenbendazole**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Final rule.

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**SUMMARY:** The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a supplemental new animal drug application (NADA) filed by Hoechst Roussel Vet. The supplemental NADA provides for revised feeding instructions for using fenbendazole in Type C medicated swine feeds to allow for restricted feeding of sows.

**EFFECTIVE DATE:** *(Insert date of publication in the Federal Register.)*

**FOR FURTHER INFORMATION CONTACT:** Janis R. Messenheimer, Center for Veterinary Medicine (HFV-135), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-7578.

**SUPPLEMENTARY INFORMATION:** Hoechst Roussel Vet, 30 Independence Blvd., P.O. Box 4915, Warren, NJ 07059, filed supplemental NADA 131-675 for fenbendazole Type C medicated swine feeds. The supplemental NADA provides for increasing the concentration of fenbendazole in Type C medicated swine feeds from 10 to 80 grams per ton (g/t) to 10 to 300 g/t to be fed at 9 milligrams per kilogram (mg/kg) (4.08 mg per pound (lb)) over a 3- to 12-day period. The supplement is approved as of April 16, 1999, and the regulations in 21 CFR 558.258(c)(1)(i) are amended to reflect that fenbendazole Type C medicated swine feeds contain 10 to 300 g/t fenbendazole and are fed at 9 mg/kg body weight (4.08 mg/lb) over a 3- to 12-day period.

The supplemental NADA approval provides for clarification of the amount of drug fed to the animals for treatment. No additional safety or effectiveness data were required. Therefore, a freedom of information summary is not required.

### **List of Subjects in 21 CFR Part 558**

Animal drugs, Animal feeds.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 558 is amended as follows:

### **PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS**

1. The authority citation for 21 CFR part 558 continues to read as follows:

**Authority:** 21 U.S.C. 360b, 371.



**§ 558.258 [Amended]***introductory text**Ann  
Maso  
OER*

2. Section 558.258 *Fenbendazole* is amended in paragraph (c)(1)(i) by removing "10 to 80" and adding in its place "10 to 300".

*mg for  
BB*

Dated: May 4, 1999

May 4, 1999

Margaret Ann Miller

Margaret Ann Miller  
Acting Director  
Office of New Animal Drug  
Evaluation  
Center for Veterinary Medicine

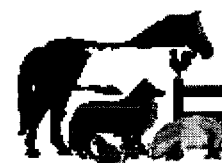
[FR Doc. 99-???? Filed ??-??-99; 8:45 am]

**BILLING CODE 4160-01-F**

**CERTIFIED TO BE A TRUE COPY OF THE ORIGINAL**

*Michael W. Belf*

Center for Veterinary Medicine



TO: A. Abbott, HF-26 12 A 17

TO: Robin Thomas, HF-27

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NADA 131-675

CVM # 9848

Instructions to HF-27: Please forward the attached documents to HFA-305 for public display when you send the certified copy of FEDERAL REGISTER document to HFA-305.

Instructions to HFA-305: Please **DISPLAY** the attached documents.

If there are any questions, please contact: Lonnie Luther, HFV-102, MPN-2, Rm 387  
Telephone (301) 594-1623 FAX (301) 594-2297

# Safe-Guard® (fenbendazole)

NDC 12799-472-02

## 20% Type "A" Medicated Article (Premix) Swine Dewormer

### DOSAGE

9 mg fenbendazole per kg body weight (4.08 mg fenbendazole per pound) to be fed as the sole ration over a period of 3 to 12 days.

### EXAMPLE OF MIXING AND FEEDING RATES FOR SAFE-GUARD® PREMIX

Average daily feed consumption		Amount of SAFE-GUARD® Premix added to each ton of swine feed based on weight and average feed consumption.					
		Treatment Period					
		3 Days		6 Days		12 Days	
Pig. Wt. (lbs.)	lbs. of Feed	lbs.	Grams	lbs.	Grams	lbs.	Grams
30	2.25	0.40	182	0.20	91	0.10	46
50	3.20	0.47	213	0.24	107	0.12	54
75	4.25	0.53	241	0.27	121	0.14	61
100	5.30	0.57	258	0.29	129	0.15	65
150	6.80	0.66	301	0.33	151	0.17	76
200	8.00	0.75	341	0.38	171	0.19	88

SAFE-GUARD® PREMIX can be safely fed to growing pigs, gilts, pregnant sows, and boars.

Feed as the sole ration for three (3) to twelve (12) consecutive days. No prior withdrawal of feed or water necessary. When feed containing SAFE-GUARD® has been blended according to the above rates based on pig weight and average daily feed consumption, and is then fed for 3-12 days, a total intake of 9 mg fenbendazole per kilogram body weight (4.08 mg fenbendazole per pound) is assured. Swine feeds containing SAFE-GUARD® can be fed pelleted or as meal. SAFE-GUARD® can be fed to pregnant sows. There is no withdrawal as SAFE-GUARD® can be fed to day of slaughter.

### GENERAL MIXING DIRECTIONS

It is recommended that SAFE-GUARD® 20% PREMIX be diluted before addition to the final feed. A dilution of one part of SAFE-GUARD® PREMIX and nine parts of grain carrier is the suggested working premix. The working premix is then blended with the complete feed mixture. Thoroughly mix both working premix and complete feed to ensure complete and uniform distribution of the SAFE-GUARD® PREMIX.

### ACTIVE DRUG INGREDIENT:

Fenbendazole 200 grams per kilogram (90.7 grams per pound).

### INERT INGREDIENTS:

Roughage Products or Roughage Products and Calcium Carbonate; and Mineral Oil or Soybean Oil.

### 3 - 12 DAY TREATMENT REGIMEN (TOTAL DOSAGE, 9 MG/KG BODY WEIGHT) FOR THE REMOVAL OF:

Lungworms: *Metastrongylus apri*, *Metastrongylus pudendotectus*.

Gastrointestinal worms: Adult and larvae (L<sub>1</sub>, L<sub>2</sub> stages, liver, lung, intestinal forms) large roundworm (*Ascaris suum*); nodular worms (*Oesophagostomum dentatum*, *O. quadrispinulatum*); small stomach worm (*Hyostrongylus rubidus*); adult and larvae (L<sub>2-4</sub> stages - intestinal mucosal forms) whipworm (*Trichuris suis*).

Kidneyworm: Adult and larvae *Stephanurus dentatus*.

MUST BE MIXED BEFORE FEEDING ACCORDING TO DIRECTIONS AND PERMITTED CLAIMS  
FOR USE IN MANUFACTURED FEEDS ONLY

CONSULT YOUR VETERINARIAN FOR ASSISTANCE IN THE DIAGNOSIS, TREATMENT, AND CONTROL OF PARASITISM

**Net Weight 25 pounds (11.34 kg)**

Safe-Guard REG TM

Hoechst Celanese Corporation

Distributed by:

**Hoechst Roussel Vet**

30 Independence Blvd.  
Warren, NJ 07059

**Hoechst**

584726 - 10/97

See other panels for cattle and zoo/wildlife animals

Approved FDA NADA 131-675 (Swine, Zoo & Wildlife Animals)



TAKE TIME



OBSERVE LABEL  
DIRECTIONS

Batch No.

Exp. Date

NADA-131-675  
NEU-12 (FET stuff)

000013

NET WEIGHT ON BAG OR INVOICE

**SWINE FEED**

FBZ

TYPE B MEDICATED FEED

**INDICATIONS**

For the removal of:

**Lungworms:** *Metastrongylus apri*, *Metastrongylus pudendotectus*

**Gastrointestinal worms:** Adult and larvae (L<sub>3</sub>, L<sub>4</sub> stages, liver, lung, intestinal form large roundworm (*Ascaris suum*), nodular worms (*Oesophagostomum dentatum*, *O. quadrispinulatum*), small stomach worm (*Hyoststrongylus rubidus*), adult and larvae (L<sub>2,3,4</sub> stages - intestinal mucosal forms) whipworm (*Trichuris suis*)

**Kidneyworm:** Adult and larvae *Stephanurus dentatus*.

**ACTIVE DRUG INGREDIENT**

Fenbendazole	1,000 - 17,740 g/ton
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**GUARANTEED ANALYSIS**

Crude Protein	not less than ____ %
Crude Fat	not less than ____ %
Crude Fiber	not less than ____ %

**INGREDIENTS**

Each ingredient must be named in accordance with the names and definitions adopted by the Association of American Feed Control Officials' Publication (AAFCO Official Publication).

**MIXING DIRECTIONS**

Mix 1.13 to 600.00 pounds with 1998.87 to 1400.00 pounds of feed ingredients to manufacture Type C medicated feeds containing 10 to 300 grams of fenbendazole per ton. The resulting Type C medicated feed is to be fed for 3 to 12 consecutive days at the rate of 0.91 to 6.80 pounds daily per 100 pounds of body weight to provide a total dose of 4.08 milligrams fenbendazole per pound of body weight.

**MANUFACTURED BY  
BLUE BIRD FEED MILLS  
ROBIN, INDIANA**

**Lot No.**

NET WEIGHT ON BAG OR INVOICE

**SWINE FEED**

FBZ

TYPE C MEDICATED FEED

**INDICATIONS**

For the removal of:

**Lungworms:** *Metastrongylus apri*, *Metastrongylus pudendotectus*

**Gastrointestinal worms:** Adult and Larvae (L<sub>3</sub>, L<sub>4</sub>, stages, liver, lung, intestinal form large roundworm (*Ascaris suum*), nodular worms (*Oesophagostomum dentatum*, *O. quadrispinulatum*); small stomach worm (*Hyoststrongylus rubidus*), adult and larvae (L<sub>2,3,4</sub>, stages - intestinal mucosal forms) whipworm (*Trichuris suis*)

**Kidneyworm:** Adult and larvae *Stephanurus dentatus*.

**ACTIVE DRUG INGREDIENT**

Fenbendazole                      10 - 300 g/ton

**GUARANTEED ANALYSIS**

Crude Protein	not less than ____ %
Crude Fat	not less than ____ %
Crude Fiber	not less than ____ %

**INGREDIENTS**

Each ingredient must be named in accordance with the names and definitions adopted by the Association of American Feed Control Officials' Publication (AAFCO Official Publication).

**FEEDING DIRECTIONS**

Feed for 3 to 12 consecutive days at the rate of 0.91 to 6.80 pounds daily per 100 pounds of body weight to provide a total dose of 4.08 milligrams fenbendazole per pound of body weight.

MANUFACTURED BY  
BLUE BIRD FEED MILLS  
ROBIN, INDIANA

Lot No.